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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-79

July 26, 1999

Stanley G. Tangalakis
Owner/President
Mercury Medical
11300 49th Street North
Clearwater, Florida 34672

Dear Mr. Tangalakis:

We are writing to you because on April 20-23, 1999 FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving the 1055 series resuscitation (CPR) Bags (Class II) and the 1019 series "Upsher" laryngoscope system (Class I), which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

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1. Failure to establish, maintain and implement procedures for receiving, reviewing, and evaluating complaints to determine whether an investigation is necessary as required by 21 CFR 820.198 (a), (b), (c), & (e). For example, there were failures that were not investigated and complaints not documented that were received by oral report, or when a device was not returned (Inspectional Observations, FDA 483, Item #s 1 & 2).

Your firm's responses dated May 18 & June 18, 1999 to FDA Item #s 1 & 2 are inadequate because they fail to address the complaints identified as not being investigated using the procedural changes incorporated in the existing procedures.

2. Failure to establish and maintain procedures for implementing corrective and preventive action including investigating the causes of nonconformities and identifying the actions necessary to correct and prevent recurrences as required by 21 CFR 820.100. For example, there was no procedure to analyze complaints on a periodic basis to trend nonconformities or failures (FDA 483, Item #s 3, 4 & 5).

Your firm's responses dated May 18, 1999 to FDA 483, Item #s 3, 4 & 5 are inadequate because they fail to address the non-conformities identified including lots of infant and child-patient valves and in-coming components that were identified as nonconforming and placed in "HOLD" status. Design controls, Corrective and Preventive Actions, Purchasing Controls, Change Control, Training, and Device Master and History Records will need to be addressed pursuant to the QS Regulations.

Your firm's response dated June 18, 1999 address the procedures for Engineering Change Orders, Control of Non-Conforming Product etc., however, there is no documentation of their use to investigate the failures and non-conformities identified during the investigation.

3. Failure to establish, maintain and implement sampling procedures (plans) to control and verify the acceptability of incoming components and finished devices as required by

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21 CFR 820.250. For example, several reports (7) failed to identify any plan or the receipt and inspection of infant/child patient valves and four reports identified a handwritten AQL that was not followed (FDA 483, Item #6).

Your firm's response dated May 18, 1999 to FDA 483, Item #6 is inadequate because it fails to address the actual sampling plan that is being implemented or provide a copy of the sampling plan matrix referred to, e.g., Mil Std 105 or the AQLs that will be used to determine a component or device's acceptability based on lot size.

4. Failure to establish and maintain procedures to ensure that all Device History Records (DHRs) are complete as required by 21 CFR 820.184. For example, processing and manufacturing steps identified in the assembly instructions for the "UPSHER" laryngoscope were not properly documented.

Your firm's response dated May 18, 1999 to FDA 483, Item # 7 appears to be adequate.

5. Failure to establish, maintain and document procedures to calibrate Test Lungs to ensure they are capable of producing valid results and establish provisions for remedial action to reestablish the limits for accuracy and precision as required by 21 CFR 820.72. For example, the service records fail to show actual test results that allow verification that specifications were met.

Your firm's response dated May 18, 1999 to FDA 483, Item #8 is inadequate because it fails to address why some results were verified and others weren't. Also your response dated June 18, 1999 fails to address or provide copies of test results that were reportedly conducted by the manufacturer.

6. Failure to establish and maintain records of acceptable suppliers pursuant to your own written procedures as required by 21 CFR 820.50(a)(3). For example, your largest component supplier was not subject to an approved and signed Supplier Quality Agreement (SQA).

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Your firm's response (identified as #10) dated May 18, 1999 to FDA 483 Item #9 fails to address the investigator's observation that supplier agreements were not approved, signed and on file.

7. Failure to establish executive responsibility and corporate policy for organization, resources and quality policy as required by 21 CFR 820.20(a) and (b).

Your firm's responses dated May 18 and June 18, 1999 state that Management Responsibility SOP will be undertaken. A copy of the procedure was not provided for review.

8. Failure to establish and maintain an Employee Training procedure with specific application to GMP requirements as required by 21 CFR 820.25(b).

Your firm's responses (identified as #9) dated May 18 and June 18, 1999 to FDA 483, Item #10 are limited to Design Controls and Validation only. All applicable QS Regulation and GMP requirements should be addressed.

Corrections to FDA 483 items not specifically noted in this letter were deemed to be corrected and the responses appeared to be adequate. Corrections to these items will be verified during the next inspection of your firm.

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no

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requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Cousins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407)475-4728.

Sincerely,

A handwritten signature in black ink, reading "Douglas D. Tolen". The signature is fluid and cursive, with a large, stylized initial 'D'.

Douglas D. Tolen
Director, Florida District